Rep. Joseph R. Pitts
Opening Statement
Energy and Commerce Subcommittee on Health
Hearing on "Reauthorization of MDUFA: What It Means for Jobs, Innovation, and Patients"
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(As Prepared for Delivery)

Congress first authorized a medical device user fee program in 2002, in the Medical Device User Fee and Modernization Act (MDUFMA). We last reauthorized the program in the Medical Device User Fee Amendments of 2007 (MDUFA), which expires September 30, 2012.

While I am glad that FDA and industry have recently reached a proposed medical device user fee agreement, the Committee did not receive it by the January 15, 2012 deadline, as set in statute.

As it is already late, I would encourage FDA and the Administration to expedite their review of the agreement so that the Committee receives it at the earliest possible date.

The proposed agreement will provide $595 million in user fees for FY2013 through FY2017 – a sum that is more than double the current user fee level of $287 million.

A key goal of the agreement is to increase predictability and transparency.

Under the agreement, together with regular Congressional appropriations, FDA should be able to hire 240 full-time review process employees, including 140 reviewers specifically for devices, over 5 years.

The increased user fees will pay for additional training for device reviewers and information technology upgrades to improve the review process.

With these new resources, FDA has agreed to measure review time in "calendar days," not "FDA days," which is an important step to providing increased predictability.

Under the proposed agreement, FDA and industry will communicate more often, and earlier in the review process, where FDA will provide the feedback that manufacturers need to go forward.

The United States is the world leader in medical device innovation. This not only benefits patients who need new, innovative treatments. It benefits our economy.

In 2008, according to the Lewin Group, the medical device industry employed 422,778 workers nationwide, paid $24.6 billion in earnings, and shipped $135.9 billion worth of products.

In 2008, in my home state of Pennsylvania, the medical device industry employed 22,233 people and paid Pennsylvania workers over $1.1 billion in earnings.

These are good jobs. Nationally, jobs in medical technology pay almost 40% higher compared to the national earnings average.

What is best for patients – and what is best for jobs – is to have a device review process that is clear, transparent, predictable, and accountable. I hope that is what the proposed agreement accomplishes.

Thank you to all of our witnesses.